Consideration of Other Regulatory Revisions for Chemical Contaminants in Support of the Six-Year Review of the National Primary Drinking Water Regulations

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ACRONYMS

ASDWA	Association of State Drinking Water Administrators
BAT	Best Available Technology
CCR	Consumer Confidence Report
CFR	Code of Federal Regulations
CMR	Chemical Monitoring Reform
CWS	Community water system
EPA	U.S. Environmental Protection Agency
EPTDS	Entry point to the distribution system
FR	*Federal Register*
HQ	EPA Headquarters
IOC	Inorganic chemical
LCR	Lead and Copper Rule
MCL	Maximum Contaminant Level
mg/L	Milligrams per liter
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-transient, non-community water system
OGWDW	Office of Ground Water and Drinking Water
PMR	Permanent Monitoring Relief
PN	Public Notification
PWS	Public water system
SDWA	Safe Drinking Water Act
SDWIS	Safe Drinking Water Information System
SMCL	Secondary Maximum Contaminant Level
SMF	Standard Monitoring Framework
SOC	Synthetic organic chemical
TCR	Total Coliform Rule
TNCWS	Transient, non-community water system
USEPA	U.S. Environmental Protection Agency
VOC	Volatile organic chemical

1.0 Introduction

1.1 Statutory Background

Under the Safe Drinking Water Act (SDWA), the U.S. Environmental Protection Agency (EPA) must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. This requirement is contained in Section 1412(b)(9) of the SDWA, as amended in 1996, which reads:

> *"The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons."*

To facilitate the quality and consistency of this regulatory review process, EPA plans to perform a series of analyses at the beginning of each review cycle, intended to target those NPDWRs that are the most appropriate candidates for revision. The Agency plans to use available, scientifically-sound data to make decisions regarding whether or not to revise a regulation. During each review cycle, EPA will review the following key information to make decisions regarding regulatory changes: health risk assessments; technology assessments; other revisions related to implementation of the regulations; occurrence and exposure analyses; and economic considerations.

For its review of other regulatory revisions, EPA focused this review on issues that are not already being addressed, or have not been addressed, through alternative mechanisms (e.g., as a part of a recent or ongoing rulemaking, in conjunction with possible chemical monitoring reform, etc.). Where appropriate alternative mechanisms did not exist, EPA considered these implementation-related concerns if the potential revision met the following criteria:

(1) It represented a potential change in the 40 Code of Federal Regulations (CFR) 141 requirements;
(2) It was "ready" for rulemaking – that is, the problem to be resolved has been clearly identified and specific option(s) have been formulated to address the problem; and
(3) It met at least one of the following conditions:
- clearly improved the level of public health protection; and/or
- represented a significant cost savings while maintaining or improving the public health protection.

Regulatory implementation issues that EPA has considered during the 1996-2002 review cycle are discussed here in this summary report.

1.2 Implementation Issues Considered for the 1996-2002 Review Period

In December of 2000, EPA headquarters (HQ) circulated a memorandum to its Regional offices requesting feedback on issues relating to the implementation of its drinking water regulations. Although the memorandum specified a 'potential set of issues' for consideration, Regions were asked to identify any other known issues related to regulatory implementation. In addition, the Association of State Drinking Water Administrators (ASDWA) was asked to confer with the States regarding implementation issues that they felt needed to be reviewed or addressed.

The number and extent of comments received from the Regions and States were limited. In response to the memorandum and the request to the ASDWA, EPA received comments from: nine EPA Regions, seven States, and the ASDWA. Of the written comments received, a few discussed issues that have already been addressed in the recently published arsenic and radionuclides NPDWRs (66 FR 6975, USEPA, 2001; 65 FR 7607, USEPA, 2000c), and others are being addressed

through ongoing mechanisms. This document summarizes the implementation issues identified by the commenters. Copies of the comments received, as well as the notice that was sent to Regions requesting comment, are available at the Six-Year Review [W-01-14] Water Docket, U.S. Environmental Protection Agency; 401 M Street, SW; EB-57; Washington, DC 20460; (202) 260-3027 between 9 a.m. and 3:30 p.m. Eastern Time, Monday through Friday. The EPA Implementation Workgroup, consisting of EPA HQ and Regional representatives, position's regarding each of the issues can be found within each of the topical sections of this document. Comments addressing issues related to the Total Coliform Rule (TCR) are addressed in a separate document.

2.0 Compliance Monitoring and Reporting

2.1 Issue Description

In developing the NPDWRs, EPA established monitoring requirements for contaminants, including frequency and location of sampling. The general monitoring framework for these chemical contaminants as set up by EPA is referred to as the Standard Monitoring Framework (SMF). This framework consists of required compliance monitoring every three, six, and nine years, depending on the occurrence of regulated contaminants, and the issuance of waivers by States. EPA has allowed the use of grandfathered data for some contaminants, and has a process for allowing States to issue waivers to PWSs for contaminants of the Phase II/V Rules (see 40 CFR 141.23 and 141.24).

Many commenters suggested that compliance monitoring schedules and waiver issuance, as currently structured, provide inadequate flexibility, and/or are inconsistently applied across different types of PWSs and different contaminant groups. Most commenters would like to see more consistent application of the regulations.

Some commenters also expressed interest in reducing recordkeeping and reporting requirements to alleviate the burden on States and PWSs. State-related reporting and recordkeeping requirements are part of 40 CFR 142, and thus are outside the scope of the Six-Year Review.

2.2 Summary of Comments and EPA Responses

2.2.1 Flexibility of Monitoring Schedules

Comment Summary: Several commenters suggested that current monitoring requirements (as related to triggers for increased monitoring, reduced monitoring, and routine monitoring) provide inadequate flexibility, and/or are inconsistently applied across different types of PWSs (e.g., ground water vs. surface water) and different contaminant groups. Several commenters stated that there is a need to have more consistent application of the regulations, particularly for chronic contaminants where maximum contaminant levels (MCLs) are based on lifetime exposure to contaminants. Related to this, commenters suggested that, in order to conserve State and PWS resources, new contaminant monitoring schedules should be coordinated with existing contaminant schedules in the SMF. Finally, others commented that the new rules should allow for reductions in monitoring of a variety of contaminants, particularly those determined to be chronic or naturally-occurring contaminants, such as arsenic and fluoride, and should not need to be monitored quarterly.

Agency Response: EPA established the SMF for all of the regulated chemical and radiological contaminants (except lead and copper, due to the need for distribution system monitoring for these contaminants). When the Chemical Monitoring Reform (CMR) effort (62 FR 36099, USEPA, 1997) proposed revisions to streamline chemical monitoring requirements (some that were less stringent than the existing framework and others that were more stringent), stakeholders and other commenters indicated that the existing framework was sufficient, and that adoption of the CMR

would be too burdensome to States. Therefore, the Agency has decided to take no further action on CMR type issues. However, the Agency has made specific efforts to coordinate recently promulgated chemical and radiological rules (arsenic and radionuclides) with the SMF (66 FR 6975, USEPA, 2001; 65 FR 7607, USEPA, 2000c). In addition, under the Arsenic Rule, new system monitoring requirements are now up to the Primacy Agency to determine, which confirms one aspect of flexibility in State oversight of PWSs.

With respect to flexibility for States in determining reduced monitoring schedules: although the Agency understands the need for PWSs to reduce monitoring where possible, if a PWS is exceeding an MCL, then there is a public health threat and the PWS should monitor on a quarterly basis or install treatment. Moreover, for an acute contaminant, such as nitrate, the Agency believes that regular monitoring is important to characterize any variations in the frequency and/or concentrations that may exceed levels of public health concern. Quarterly monitoring is a tool for States and EPA to track non-compliance with MCLs, as well as to encourage systems to rectify the problem as expeditiously as possible. However, States have the flexibility to evaluate situation-specific circumstances and reduce systems on increased monitoring from quarterly to annual samples, and/or waive the sampling requirements after a minimum of criteria are achieved.

2.2.2 Waiver Issuance and Vulnerability Assessment

Comment Summary: Several commenters pointed to a need for broader flexibility in determining not only the appropriate timing for contaminant monitoring, but also in identifying which contaminants need to be monitored. Specifically, commenters indicate that systems should not be required to monitor for contaminants that are not found in their geographic areas, as based on previous monitoring results, source water assessment data, vulnerability assessments, and hydrogeology. Commenters also indicated the need for flexibility in setting the vulnerable times for pesticide monitoring, based on area-specific temporal patterns.

Agency Response: States that have Primacy for the drinking water regulations are responsible for their waiver programs. With respect to waiver flexibility and the use of monitoring waivers, the Agency believes that States have sufficient flexibility to issue Statewide waivers and PWS-specific waivers. For example, States can use the source water assessments, if they meet the minimum requirements that are needed to issue a susceptibility waiver.

With respect to flexibility in determining vulnerable periods for pesticides: the Agency notes that statistical studies of sampling strategies in surface water (Battaglin and Hay, 1996) have shown that incorporating sampling during spring and early summer runoff periods provides a more accurate representation of annual occurrence than random quarterly sampling (that may avoid these months). Ground water studies (Pinsky *et al.*, 1997) suggest that the more vulnerable ground water settings also show peaks during these periods. However, the Agency has not received any new scientific data that suggests it is appropriate to revisit the vulnerable times for pesticide monitoring, based on the concept that targeted monitoring would better represent a consumer's true contaminant exposure.

EPA is looking at the vulnerability assessment issue through another mechanism. The Agency is preparing a comprehensive report on PWS vulnerability to the range of potential drinking water contaminants. The comprehensive report will present a recommended approach to applying vulnerability concepts to drinking water programs.

3.0 Lead and Copper Rule Requirements

3.1 Issue Description

EPA published revisions to the Lead and Copper Rule (LCR) on January 12, 2000 (65 FR 1950; USEPA, 2000a). The revisions were designed to provided clarifications, and to streamline monitoring and reporting burdens for PWSs and State drinking water agencies. As part of these revisions, EPA added language to the LCR which clarifies requirements and corrects oversights in the original rule. The revisions do not affect the lead and copper maximum contaminant level goals, action levels, or other basic regulatory requirements to monitor for lead and copper at the tap and to optimize corrosion control.

Commenters made numerous suggestions for further streamlining monitoring, recordkeeping, and reporting requirements. As noted above, State recordkeeping and reporting requirements are outside the scope of the Six-Year Review, as they are part of 40 CFR 142.

3.2 Summary of Comments and EPA Responses

3.2.1 Suggestions for Cost and Burden Reduction

Comment Summary: Commenters made several suggestions on ways to reduce burden to PWSs and States, including: reduced monitoring requirements, providing monitoring waivers, discontinuing the copper NPDWR or changing it to a secondary standard, and moving lead and copper into the SMF schedule of sampling once every 3/6/9 years. Commenters suggested that EPA review the non-transient, non-community water system (NTNCWS) sampling and mitigation requirements to allow for meaningful application of the rule at these systems. Suggestions included: allowances for fewer than five samples at systems that only have one or two taps, and allowances for "automatic flushing systems" as a means of controlling lead and copper levels.

Agency Response: EPA reduced the monitoring requirements for lead and copper in the January 2000 revisions to the LCR and does not believe that further reductions, particularly for copper, can be made without undermining the level of public health protection, which is prohibited by the SDWA. Regarding monitoring requirements for lead in the LCR, the Agency believes that any further revisions would not provide adequate public health protection for members of sensitive populations (i.e., pregnant women and children six years of age or younger) for exposure to lead. However, if new peer-reviewed scientific information becomes available it will be considered.[1]

EPA considered special allowances for NTNCWSs as part of the January 2000 revisions to the LCR. However, EPA decided at that time to retain the current requirement because the Agency did not have sufficient scientific data that would support reasonable alternatives for all NTNCWSs.

The issues raised by the commenters were not new; they were considered for the January 2000 revision to the LCR. At this time, the Agency has not received any new scientific data that suggests it is appropriate to revisit the lead and copper rule requirements.

[1] Peer-reviewed data are studies/analyses that have been reviewed by qualified individuals (or organizations) who are independent of those who performed the work but who are collectively equivalent (i.e., peers) to those who performed the original work. A peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternative interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work products and of the documentation that supports them (USEPA, 2000d).

3.2.2 Sampling Methodology and Strategy

Comment Summary: Commenters suggested that the current approach to sampling strategy limits a PWS operator's ability to identify sampling sites. The comments note that the current 'tiered approach' to sampling plans, which is designed to target sites likely to have high levels of lead at the tap, has raised public concern about why locations where children are more likely to be exposed to lead and copper (such as schools and day care centers) are not better sampling points.

Agency Response: The Agency considered modifying the sampling protocol as a part of the January 2000 revisions to the LCR but did not believe that there was sufficient scientific data on which to base a revised protocol. EPA currently believes that regularly utilized household taps are the most appropriate sampling locations to determine whether consumers are being exposed to high levels of lead and copper in drinking water. If a PWS does not have enough sites that meet the tiering criteria, the January 2000 revisions to the LCR provide PWSs with the authority to complete their sampling pool with representative sites throughout the distribution system. However, at this time, EPA does not have any new information that demonstrates that sampling at other locations, which might be more within the control of the PWS operator, or modifying the sampling protocol would maintain the same level of public health protection. However, if new peer-reviewed scientific information becomes available, it will be considered.

4.0 Monitoring for Cyanides

4.1 Issue Description

EPA published the current NPDWR for cyanide on July 17, 1992 (57 FR 31776, USEPA, 1992). Under this regulation, PWSs may receive a waiver for cyanide monitoring. Without a waiver, ground water systems are required to monitor for cyanide once every three years, while surface water systems are required to monitor annually. All samples must currently be collected from the entry point to the distribution system (EPTDS).

Comments regarding cyanide addressed the possibility of raw water monitoring due to possible formation of cyanogen chloride after chlorination. Other commenters identified the need for a rule revision relating to an error in the Best Available Technology (BAT) specified for cyanide in the CFR.

4.2 Summary of Comments and EPA Responses

Comment Summary: A variety of comments were received on the cyanide issue, ranging from those that believe that no further expansion of cyanide monitoring is needed to a commenter that believes monitoring of cyanide and nitrites is the "second highest priority." It was suggested that the Agency consider requiring cyanide monitoring in raw water, since monitoring treated water (i.e., after chlorine disinfection) provides no useful data on the presence of cyanogen chloride formation after chlorination. One commenter indicated that they believe that the treatment of raw water containing cyanide should be addressed as a regional issue, particularly for many Western States. Another commenter expressed concern that monitoring for cyanide in raw water would "skew the analysis of risk reduction" and would potentially take away the ability to identify contaminant levels to which consumers are actually exposed. This commenter also recommended that it might be better to "use raw water monitoring as a screen, and only require treated water testing when there is a detect." Comment was also received pointing out that the BAT for cyanide had been clarified as being alkaline chlorination in an EPA advisory, and should be changed in the regulation.

Agency Responses: Regarding cyanide monitoring issues: EPA has not received any new data and recognizes that more research may be needed to determine the extent of the problem. If further research indicates this is a widespread and high-priority issue, then the Agency may consider it in an

upcoming rulemaking (e.g., Distribution System Rule). EPA suggests that PWSs and States with cyanide and/or cyanogen chloride problems should take advantage of information in the "Public Water System Warning" Memo (USEPA, 1994), which deals directly with this issue. In addition to the required monitoring, States also have the flexibility to monitor raw source water samples for cyanide as well as monitor for cyanogen chloride in the distribution system.

EPA acknowledges that in 40 CFR 141.62(c), the BAT incorrectly specifies "chlorine" for cyanide. It should specify "alkaline chlorination." EPA plans to correct this error through a technical amendment to the cyanide NPDWR in the future. In the meantime, water systems and States should continue to be guided by the small system compliance technology list published September 1998, which correctly list the technology as alkaline chlorination and the "Public Water System Warning" (USEPA, 1994; USEPA, 1998b).

5.0 Monitoring for Nitrites

5.1 Issue Description

EPA published the current NPDWR for nitrite on January 30, 1991 (56 FR 3526, USEPA, 1991), establishing an MCL of 1.0 mg/L, and the requirement that all PWSs must monitor for nitrite at each EPTDS. States cannot issue waivers for nitrite monitoring. The federal regulations require that one nitrite sample be collected in the 1993-2001 compliance period. Future or more frequent nitrite monitoring is left to the discretion of the State. Many States do require their PWSs to monitor for nitrite once every three years, on the same monitoring schedule as all other inorganic chemicals (IOCs) (except nitrate, which is required to be monitored annually for all systems). As with cyanide monitoring, nitrite samples are required by the federal regulations to be collected at the EPTDSs. However, for PWSs which have a sufficiently high level of ammonia in their water, nitrite may be found at elevated levels in distribution systems, not at the EPTDSs. In the presence of a sufficient amount of a strong oxidant (e.g., chlorine dioxide, free chlorine, or ozone), nitrite can be oxidized to nitrate.

Comments regarding nitrite monitoring included requests for more flexibility in determining sampling location. With more flexibility, commenters suggested that States could make situation-specific adjustments to monitoring location based on monitoring results or concern over elevated nitrite levels due to chloramination.

5.2 Summary of Comments and EPA Responses

Comment Summary: Several commenters recommended that EPA provide States with the flexibility to require routine nitrite monitoring in the distribution system (rather than the EPTDS) when it appears to be the most appropriate location for that contaminant, and to require ammonia raw water sampling when appropriate. Commenters believe that changing the sampling point from the EPTDS to some point in the distribution system will affect PWSs with high levels of ammonia in raw water, especially if treatment installation is required. Another commenter recommended that EPA consider requiring distribution monitoring if an entry point result is greater than 50 percent of the MCL. Other commenters reported that chloramination may increase the likelihood of finding elevated nitrite levels in distribution systems, and that it would therefore seem reasonable to require monitoring in finished water where nitrite levels would be highest.

Agency Responses: As stated above, although free chlorine and other strong oxidant disinfectants will usually oxidize nitrite to nitrate in a water sample, EPA believes that this may not occur in all chlorinated water supplies. This issue was addressed by the Agency in the *Federal Register* Notice entitled "Analytical Methods for Chemical and Microbiological Contaminants and Revisions to Laboratory Certification Requirements" (64 FR 67449, USEPA, 1999). Some research is underway,

as part of the Distribution System Rule development, to look at the nitrification issue. However, EPA recognizes that more data/research may be necessary. If further research indicates that this is a widespread issue, the Agency may consider it in an upcoming rulemaking.

6.0 Monitoring and Public Notification for Fluoride

6.1 Issue Description

Fluoride is unique as a drinking water contaminant because of its beneficial effects at low level exposures, and because it is voluntarily added to some drinking water systems as a public health measure for reducing the incidence of cavities among the treated population.

As part of the review of possible "other regulatory revisions," EPA has identified two possible issues related to the regulation of fluoride in drinking water. The first issue is related to the timeliness of the public notification requirement associated with exceedances of the SMCL. PWSs are required to notify the public if the fluoride secondary maximum contaminant limit (SMCL) is exceeded within 12 months of the initial exceedance. EPA is currently reviewing the health effects of fluoride.

The second pertains to the issue that current monitoring for fluoride may not be sufficient for systems that fluoridate. Under the current regulations, ground water systems are required to monitor for fluoride once every three years and surface water systems to monitor annually. This monitoring scenario is consistent with monitoring requirements for other naturally-occurring IOCs (other than lead and copper) but does not consider the addition of fluoride for beneficial purposes that occurs at some water systems.

6.2 Summary of Comments and EPA Responses

Comment Summary: Commenters expressed concern about the timeliness of the public notification (PN) requirement associated with exceedances of the SMCL. Currently, as stated above, PWSs that exceed the fluoride SMCL of 2.0 mg/L are required to notify their customers within 12 months of the exceedance. Concern has been raised that this requirement is not sufficiently timely since dental fluorosis occurs as a result of exposure to high levels of fluoride while the tooth enamel is being laid down. Waiting 12 months to provide PN means that young children may be exposed to high levels of fluoride during the time at which they are most vulnerable.

Commenters raised concern that the current monitoring for fluoride may not be sufficient for systems that fluoridate. More frequent monitoring may be necessary for systems that fluoridate because fluoride does not degrade or decrease in concentration in the distribution system (unlike chlorine). In particular, concentrations of fluoride may increase above acceptable levels where evaporation of water may occur, such as in a storage tank. Thus, commenters are suggesting that more frequent monitoring may be appropriate to ensure that this does not occur.

Agency Response: Although PN requirements are not part of the NPDWR for fluoride, and are thus outside of the scope of this review, EPA will consider revisions to the fluoride PN requirements only if it becomes appropriate to revise the fluoride NPDWR in the future similarly if it is appropriate to revise the fluoride NPDWR in the future, EPA will consider the suggestion that more frequent monitoring may be necessary for systems that fluoridate because fluoride does not degrade or decrease in concentration in the distribution system.

7.0 Consumer Confidence Report and Public Notification Requirements

7.1 Issue Description

EPA requires CWSs to develop annual drinking water quality reports for distribution to their customers. Consumer Confidence Report (CCR) and PN requirements are national in scope, with CCR issues affecting only CWSs, and PN issues affecting all PWSs. Changes to CCR and PN requirements affect State drinking water agency oversight and compliance determination activities, and affect the level of reporting burden for PWSs nationwide. CCR requirements do not apply to NTNCWSs and transient, non-community water systems (TNCWSs).

7.2 Summary of Comments and EPA Responses

Comment Summary: Several commenters believed that CCR language requirements are too prescriptive, and do not provide States with enough flexibility. Commenters believe that EPA should review the CCR requirements to ensure that flexibility is retained. Some commenters expressed concern that the inclusion of mandatory language reduces the "readability" of the document for the general public. Commenters also believed that CCR and PN requirements should be consistent with one another, and that PN requirements should be simplified, or even eliminated, because the PN requirements generate additional paperwork and create unnecessary violations that have no impact on public health.

Agency Response: Many of the issues raised by the commenters have been brought up before and were addressed in the recent CCR and PN Rules (65 FR 25982, USEPA, 2000b; 63 FR 44512, USEPA, 1998a). Both rules already provide a lot of flexibility for States. In any case, the Agency does not consider the recently published CCR and PN Rule requirements to be part of the NPDWR, as defined under SDWA section 1401. Therefore, these issues are not considered within the scope of this Six-Year Review.

8.0 Re-Evaluation of Risk for Requiring NTNCWS Monitoring

8.1 Issue Description

In general, NTNCWSs are subject to the same monitoring and reporting requirements as CWSs. Some commenters suggested that EPA conduct risk and exposure assessments to determine whether NTNCWSs should continue to be regulated in the same manner as CWSs, which tend to serve a larger proportion of the population over longer time periods.

8.2 Summary of Comments and EPA Responses

Comment Summary: Some commenters suggested that EPA conduct additional research on the amount and percentage of water consumed at NTNCWSs and establish a risk assessment for individuals using these types of systems. Others recommended that EPA work with States and other stakeholders to develop a consistent approach to regulating NTNCWSs. One specification was that EPA needs to review non-acute contaminants in order to assure that the limited exposure associated with NTNCWSs actually presents a health risk worthy of regulation.

Agency Response: A workgroup within EPA's Office of Ground Water and Drinking Water is evaluating risk and exposure as they pertain to NTNCWS monitoring requirements.

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